

REMARKS

Claims 1, 2, 4-12, 16 and 17 currently appear in this application. The Office Action of December 29, 2005, has been carefully studied. These claims define novel and unobvious subject matter under Sections 102 and 103 of 35 U.S.C., and therefore should be allowed. Applicant respectfully requests favorable reconsideration, entry of the present amendment, and formal allowance of the claims.

Double Patenting

Claims 1-2 and 5-16 are rejected under the judicially created doctrine of obviousness-style double patenting as being unpatentable over claims 1-14 of U.S. Patent No. 6,686,517.

This rejection is respectfully traversed. Submitted herewith is a terminal disclaimer signed by the Attorney of Record.

Rejections Under 35 U.S.C. 112

Claims 1, 2 and 4-17 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The Examiner alleges that the specification fails to provide a written description of the broad genus of *Raphanus sativa* plants.

This rejection is respectfully traversed. It is respectfully submitted that the claims are not drawn to a broad genus, as alleged by the Examiner, but to one specific species, namely, *Raphanus sativa*, which is far more limited than a genus. Members of a species are cross-fertile, while members of a genus generally are not cross-fertile.

It is respectfully submitted that the limitation proposed by the Examiner, limiting the claims to one specific *Raphanus sativa* line, namely, the V33, would be overly limiting. This limitation would allow anyone to make derivatives of V33 by crossing V33 with another *Raphanus sativa* plant, and freely use these derivatives.

The written description clearly describes *Raphanus sativa* plants in general, as those having a high anthocyanin level, as in paragraph 0008. The written description is nowhere limited to line V33. In fact, the specification at page 2, lines 6-26, define the *Raphanus* plants as those that have an anthocyanin content of preferably at least 2, 5, 10, 20, 50 or 75% of the anthocyanin content of the *Raphanus sativa* line V33. The specification at page 4, lines 13-17, states that the *Raphanus* plant of the invention preferably is a plant of the species *Raphanus sativa*, more preferably the plant is obtained through breeding and selection from the *Raphanus sativa* lines CGN 6924, CGN 7240, or both. Most

preferably, the *Raphanus* plants that can be used are obtained through breeding and selection from the *Raphanus sativa* line V33. Methods of breeding and selection the *Raphanus* plants are well known in the art, as described in the specification at page 4, lines 17-30.

This language, taken directly from the specification, clearly encompasses *Raphanus sativa* plants in general that have the high anthocyanin contents as claimed. If the written description requirement is for the purpose of warning an innocent purchaser of his infringement of the patent, then Applicant does not understand how the written description of the present application can fail to warn an innocent purchaser that *Raphanus sativa* plants other than line V33 are encompassed. It is clear that *Raphanus* plants having the required concentration of anthocyanins are contemplated by the application.

As noted above, the written description herein furnishes all of the information required for obtaining the claimed plants of the species *Raphanus sativa*, not only V33. It is respectfully submitted that it is not necessary to describe all known prior art methods and material in order to satisfy the written description requirements. Methods such as breeding and selection are well known in this art and are also described on page 4 of the application.

The *Raphanus sativa* V33 that was deposited has the herein claimed anthocyanin levels, and one skilled in the art can readily breed plants having anthocyanin levels that are at least a certain percentage of the anthocyanin levels.

Attention is directed to *Enzo Biochem, Inc. v. Gen-Probe, Inc.* 296 F.3d 1316, 1325; 63 USPQ2d 1609 (Fed. Cir. 2002), wherein it is stated,

"reference in the specification to a deposit in a public depository, which makes its contents accessible to the public when it is not otherwise available in written form, constitutes an adequate description of the deposited material sufficient to comply with the written description requirement."

The reference line V33 has been deposited. However, there is no requirement to deposit other *Raphanus sativa* plants that have the required amount of anthocyanin. One skilled in the art can determine if another line of this species has the required anthocyanin levels without undue experimentation. Example 4 in the present specification provides explicit guidance on how to determine if a plant has the requisite amount of anthocyanin. Additionally, those skilled in the art of plant husbandry can readily breed and select *Raphanus* plants that have the desired anthocyanin levels. The V33 line provides guidance for what plants are covered, and one skilled in the art can produce other lines that have similar anthocyanin levels. Since the specification

provides clear methods for determining if a plant has the required anthocyanin levels, and how one can breed such plants without undue experimentation, there is no requirement to deposit other *Raphanus sativa* plants that have the required amount of anthocyanin.

As the Examiner is well aware, there is a requirement for deposit when there is no other way to describe the invention so that the public in possession of what the inventor claims. As noted in MPEP Section 2163, a specification may show actual reduction to practice by describing testing of the claimed invention or, in the case of biological material, by specifically describing a deposit made in accordance with 37 CFR 1.801 *et seq.* In the present case, Applicant has described breeding methods for obtaining *Raphanus sativa* plants that contain more than 800 nmol/g of fresh sprout material. Therefore, there is no reason to require a deposit of each such plant.

Claims 1, 2 and 4-17 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The Examiner states that the rejection of claims 4 and 17 is not based on the ability to make a *Raphanus sativa* plant, but the fact that the claims do not state that the claimed *Raphanus sativa* plant has been deposited.

This rejection is respectfully traversed. Applicant agrees that claim 1 is not limited to the line V33, as explained above. However, the question to be asked with respect to the enablement requirement is whether or not the skilled person is able to make the plants over the full range claimed.

It is respectfully submitted that one skilled in the art is fully capable of making all of the plants of the breadth claimed, herein, namely, plants having anthocyanins at a level of at least 800 nmol per gram fresh weight of sprout, whereby the majority of anthocyanins have a moiety of the structure of formula 1. Example 4, beginning on page 12 of the specification as filed, provides detailed instructions as to how to extract anthocyanins from a plant to determine the anthocyanin content of any given plant.

One skilled in the art of plant husbandry can make plants over the breadth claimed without trial and experimentation. The present specification provides various means to enable the skilled person to make these plants. One can use the reference line V33, cross this line with another *Raphanus sativa* line, and select purple progeny. Alternatively, one can start from other available plant material (for example, lines CGN 6924 and CGN 7240) and screen this material for purple sprout coloring and for anthocyanin

content. While crossing and selection may require time, but no undue experimentation is required. This process is described in the specification as filed at page 10, Example 1.

The Examiner uses the very old reference Savoski et al. (1974) as supporting evidence that undue trial and error would be required because Savoski et al. teach that anthocyanin accumulation in the roots (not in the sprouts) is genetically complex and unpredictable. Applicant does not claim plants having certain anthocyanin levels in the roots, which may require undue trial and error to produce such plants. Applicant claims plants having at least 800 nmol/g fresh weight anthocyanin in the sprouts.

It is respectfully submitted that it is not necessary to understand the genetic basis of anthocyanin accumulation in order to enable one skilled in the art to make plants of the invention. Understanding anthocyanin genetics may indeed be complex, but such understanding does not contribute anything to the enablement of the invention. Vice versa, the lack of such understanding does not show that one skilled in the art requires undue experimentation to make the claimed plants.

It is explicitly taught in the specification at page 16, lines 20-24, that if two of the seeds of the deposit are germinated and the plants are crossed with each other or

selfed, all of the progeny will also produce dark purple sprouts. That is, V33 is a line that does not divide out green descendants, i.e., all progeny sprouts are dark purple, like the parents. These progeny can again be crossed or selfed, and they will retain the dark purple colored sprouts of the parents. Thus, many *Raphanus sativa* plants can be made in this way, all of which contain at least 800 nmol/g fresh weight anthocyanins.

Alternatively, one can screen *Raphanus sativa* plants from public gene banks for *Raphanus sativa* plants having the ability to produce sprouts with at least some purple coloring. These plants can be selfed and/or crossed for several generations, and progeny can be selected having dark purple colored sprouts, all as described in Example 1, page 10 and on page 4, lines 18-24. Example 1 teaches that, within about 568 *Raphanus sativa* lines, about 14 produced sprouts with some purple coloring (about 2.5%). Example 1 further teaches that in this way plants that produce sprouts having >6000 nmols anthocyanins per gram fresh weight can be made (Table 1, page 16). This type of screening, crossing and selection does not require undue experimentation, especially because visual selection, based on cotyledon color, is possible, and, therefore large trays of sprouts can be quickly screened for individuals having a purple color. The sprouts with purple

cotyledons can be selected and crossed and/or selfed, until the cotyledon color is dark purple and the genetic inheritance of cotyledon color is such that all progeny have the parental purple color.

As mentioned previously, the invention teaches that crossing and selection can be used to make sprouts having very high anthocyanin levels and being of dark purple color. On page 10, lines 20-245, it is stated that V33 is a line that does "not divide out green descendants", i.e., all progeny sprouts are dark purple, like the parents. The invention therefore shows that, surprisingly, a genetically stable inheritance of sprout anthocyanin levels can be achieved by simple visual selection (without knowledge of the underlying genetics). There is no need to understand the genetics by which all progeny sprouts are dark purple, and one can cross plants without undue experimentation.

It is respectfully submitted that Savoski et al. in fact support patentability of the claimed invention. Applicant has demonstrated that it is experimentally easy to select purple sprouts and to accumulate high levels of anthocyanins in the sprouts. This is contrary to what would have been expected based on Savoski et al.

It is respectfully submitted that the present specification and seed deposit fully enable any one skilled in

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the art of plant husbandry to make all of the plants claimed over the entire scope of plants claimed using simple crossing/selfing and selection based upon sprout color and anthocyanin analysis.

Art Rejections

Claim 16 is rejected under 35 U.S.C. 103(b) as being anticipated by Giusti et al.

This rejection is respectfully traversed. Claim 16 recites a method for producing anthocyanin comprising steps (a) - (d). Step (a) involved growing plants as defined in claims 1, 2 and 4. That is, the method is limited to using *Raphanus sativa* plants comprising at least 8000 nmol/g fresh weight sprout. The Examiner has conceded that such plants are not disclosed in Giusti et al. Therefore, since Giusti et al. do not disclose plants used in the method of claim 16, Giusti et al. cannot possibly anticipate the claimed method.

Claims 13-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Giusti et al. in view of Khare et al. and further in view of Poindexter et al.

As claims 13-15 have been cancelled without prejudice, it is respectfully submitted that this rejection is now moot.

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In view of the above, it is respectfully submitted
that the claims are now in condition for allowance, and
favorable action thereon is earnestly solicited.

Respectfully submitted,

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